

COVID-19 Vaccine Safety Technical (VaST) Subgroup Technical Report

March 29, 2021

The Advisory Committee on Immunization Practices (ACIP) COVID-19 Vaccine Safety Technical (VaST) Subgroup has reviewed post-authorization Covid-19 vaccine safety data on a weekly basis since the start of the U.S. vaccination program. Updates of VaST activities have been presented at ACIP meetings that are open to the public on January 27 and March 1. The VaST Subgroup provides this written update to the public, in the absence of a scheduled ACIP meeting this month.

As of March 29, 2021, there had been a total of 143 million doses administered in the United States (Pfizer-BioNTech: 72,981,111; Moderna: 67,249,447; Johnson & Johnson/Janssen: 3,090,712; Unknown: 141,421). The VaST Subgroup has reviewed data from multiple U.S. safety monitoring surveillance systems conducted by different federal agencies and other partners including:

Passive surveillance systems

Vaccine Adverse Event Reporting System (VAERS)

Department of Veterans Administration (VA) Adverse Drug Events Reporting System (ADERS)

Department of Defense VAERS reports

Active surveillance systems

v-safe

Vaccine Safety Datalink (VSD) Rapid Cycle Analysis Department of VA Active Surveillance System Food and Drug Administration (FDA) Centers for Medicare and Medicaid Services (CMS) Rapid Cycle Analysis

Studies and registry

v-safe pregnancy registry VSD Mortality Study Vaccine safety monitoring in skilled nursing facilities

Summary of VaST Subgroup observations as of 03/29/2021:

- Rare cases of anaphylaxis following COVID-19 vaccination were identified early in the vaccination program; FDA and CDC revised educational materials and clinical guidance.
- Consistent with clinical trial data, local and systemic reactions are commonly reported following vaccination for all individuals and for pregnant women.
- Data from passive systems suggest that case reports are not higher than expected based on rates of all-cause morbidity and mortality.
- Pregnancy and birth outcomes following vaccination appear consistent with rates reported in the literature.
- In the active surveillance systems (rapid cycle analyses), pre-specified outcomes are actively monitored; no statistical signals have been reported to date with >10 million doses administered across systems.
- Adverse events following COVID-19 vaccination are being monitored through passive and active systems. VaST will continue to update the ACIP COVID-19 vaccines workgroup, ACIP secretariat and ACIP on a regular basis.

Past reports from the VaST Subgroup to ACIP:

VaST assessement of safety data

January 27 🔼

March 1 🔼

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